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Summary of Safety and Effectiveness for the Distal Radius Fracture Repair System

submitted by
Hand Innovations, Inc.
8905 SW 87 Avenue
Miami, FL 33176-2227
Phone: 1 (800)-800-8188

Contact Person: Al Weisenborn
Device Trade Name: Distal Radius Fracture Repair System
Common Name: Distal Volar Radius Plate, Dorsal Nail Plate and Jig Set
Classification Name: Plate Fixation Bone per 21 CFR § 888.3030

Identification of a Legally Marketed Predicate Device

The Hand Innovations, Inc. Distal Radius Fracture Repair System is substantially equivalent to Distal Volar Fracture Repair System that is legally marketed and distributed by Hand Innovations, Inc.

Device Description

The Distal Radius Fracture Repair System (DRFRS) was previously cleared under 510(k) No. K030198. The system consists of a volar stabilization plate, bone screws, fixation pegs, dorsal intrafocal nail-plate, three fixed angle bone pegs and two locking screws. This 510(k) is being submitted as a modification to the original 510(k) No. K030198 in order to add accessories to the DRFRS.

The Distal Volar Radius Plate (DVR) consists of a stabilization plate, bone screws, and fixation pegs. The 3.5 mm screws are used to affix the proximal segment of the plate to the diaphysis. Pegs or screws are used for the distal bone fragment(s).

The Distal Dorsal Nail-Plate (DNP) is a bone stabilization device consisting of an intrafocal nail-plate to which three-fixed angle bone pegs and two locking screws are attached. It has a narrow distal plate-like section that lies on the surface of the distal fragment and a proximal nail-like section that is introduced into the diaphysis of the radius through the fracture site. Fixed angle pegs are used to fix the distal fragment(s) to the plate section and locking screws are used to lock the proximal fragment inside the radial shaft.

Other components used in the implantation process are identified as the DNP Jig Set of Stainless Steel SST 17-4. These items consist of the DNP Jig drill guide, screw jig and screw guide.

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A standard awl, which is a manual surgical instrument, used to enlarge the size of a hole or tunnel by rotary movement is a catalog item manufactured by K-Medic (catalog no. KM-48-336).

Description of Modifications

This submission describes two accessories that are being added to the Distal Radius Fracture Repair Systems, fragment plates and a "K-Type" wire.

The fragment plates are essentially smaller implementations of the existing Distal Dorsal Nail-Plates and Distal Volar Radius Plates. The fragment plates are intended for the attachment of small bone fragments. The fragment plates will be available in the four versions: right, left, straight, and "Y."

The fragment plates are made from the same titanium (ASTM F 136 – 96) as the existing Distal Dorsal Nail-Plates and Distal Volar Radius Plates cleared via K030198. The plates are intended to be fastened to bone using the 2.5 mm titanium screws that were cleared via K030198.

The K-Wires that will be supplied with the Distal Radius Fracture Repair System are primarily intended for intraoperative use to temporarily locate bone plates or for interfragmental fixation.

Even though the K-Wire is intended primarily for intraoperative use, if desired by the surgeon, the K-Wires may permanently implanted. The K-Wires are made from the same titanium (ASTM F 136 – 96) as the existing pins and screws.

Three variations of the right and left distal volar plates have been added to accommodate the anatomies of larger and smaller patients. The list of manual surgical instruments included in the Distal Radius Fracture Repair System has been updated.

Intended Use

The Distal Radius Fracture Repair System is intended for the fixation of fractures and osteotomies involving the distal radius.

Summary of Technological Characteristics

A 15-point comparison of technological characteristics of the Hand Innovations, Inc. Distal Radius Fracture Repair System and the predicate device was performed. The devices were found to be substantially equivalent.

Summary of Performance Data

The Hand Innovations, Inc. Distal Radius Fracture Repair Systems comply with the following standards, practices, and guidances:

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- ASTM F366 – 82 (Reapproved 2000), Standard Specification for Fixation Pins and Wires
- ASTM F 136 – 96, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy (R56401) for Surgical Implant Applications.

The Hand Innovations, Inc. Distal Radius Fracture Repair System is substantially equivalent to Distal Volar Fracture Repair System that is legally marketed and distributed by Hand Innovations, Inc. This has been demonstrated through a 15-point technological comparison of features and a 3-parameter comparison of mechanical performance.

The implantable and tissue contact materials used to fabricate the Distal Radius Fracture Repair System and Instruments have a long history of safe usage in medical devices. Since the Hand Innovations, Inc. Distal Radius Fracture Repair Systems meet the requirements of the stated standards and embody technological characteristics essentially identical to the predicate device, we believe the device is safe and effective and performs as well as or better than the predicate device. The Distal Radius Fracture Repair System will be manufactured per specifications using good manufacturing practices that ensure the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 1 2003

Mr. Al Weisenborn
Hand Innovations, Inc.
8905 SW 87 Avenue
Miami, FL 33176-2227

Re: K032705
Trade/Device Name: Distal Radius Fracture Repair System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: LXT
Dated: August 27, 2003
Received: September 2, 2003

Dear Mr. Weisenborn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

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510(k) Number (if known): K032705

Device Name: Distal Radius Fracture Repair System

Indications for Use:

The Distal Radius Fracture Repair System is intended for the fixation of fractures and osteotomies involving the distal radius.

for Mark N Milleson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032705

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)